

REMARKS

The 35 USC §103(a) Rejections

Claims 6, 8-10, 12 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over **Brey** et al. (1992) in view of **Georgiou** et al. (1994) and further in view of **Haseltine** et al. (1991), **Kang** (1993) and **Rodman** (1997). This rejection is respectfully traversed.

The claims are drawn to induction of cellular and humoral anti-HIV-1 immune responses in animals using an attenuated bacterial host that expresses HIV-1 reverse transcriptase.

The Examiner contends that **Brey** et al. is directed to an attenuated strain of enteroinvasive bacteria that express a peptide or protein related to an epitope of malaria parasites. The bacteria can induce protective immune response against malaria. **Georgiou** et al. disclose recombinant DNAs that are suitable for expressing heterologous antigen on the surface of an enteric microorganism. The DNA construct encodes fusion protein that comprises a Lpp signal sequence, a portion of OmpA membrane protein and a heterologous antigen of interest. **Haseltine** et al., **Kang** and **Rodman** all disclose sequences for HIV-1 tat protein.

The Examiner concludes that it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to express the HIV-1 tat gene provided by **Haseltine** et al. (1991), **Kang** (1993) or **Rodman** (1997) as an Lpp-OmpA-Tat fusion protein, as suggested by **Georgiou** et al. (1994), in the *S. typhimurium* expression system described by **Brey** et al. (1992), since **Brey** and colleagues teach that this system is useful for generating strong immune responses against the antigen of interest. Applicant respectfully disagrees.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (M.P.E.P §2143).

Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness because the cited prior art references do not teach or suggest any use of reverse transcriptase as claimed herein. Hence, the cited prior art does not

provide the requisite motivation to modify or expectation of successfully producing Applicant's claimed method. Accordingly, Applicant respectfully request that the rejection of claims 6, 8-10, 12 and 13 under 35 U.S.C. §103(a) be withdrawn.

Claims 6, 8-10, 12 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over **Hone** et al. (1996) in view of **Georgiou** et al. (1994) and further in view of **Haseltine** et al. (1991), **Kang** (1993) and **Rodman** (1997). This rejection is respectfully traversed.

Hone disclosed induction of humoral immune response by an attenuated *Salmonella* vaccine vector expressing HIV-1 gp120 fusion protein. Other references have been discussed above.

The Examiner contends that it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to express the HIV-1 tat gene provided by **Haseltine** et al. (1991), **Kang** (1993) or **Rodman** (1997) as an Lpp-OmpA-Tat fusion protein, as suggested by **Georgiou** et al. (1994), in the *S. typhimurium* expression system described by **Hone** et al. (1996), since **Hone** and colleagues teach that this system is

useful for generating strong immune responses against the antigen of interest. Applicant respectfully disagrees.

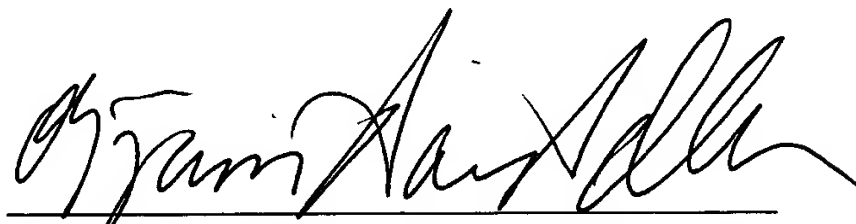
As discussed above, Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness because the cited prior art references do not teach or suggest any use of reverse transcriptase as claimed herein. Hence, the cited prior art does not provide the requisite motivation to modify or expectation of successfully producing Applicant's claimed method. Accordingly, Applicant respectfully request that the rejection of claims 6, 8-10, 12 and 13 under 35 U.S.C. §103(a) be withdrawn.

This is intended to be a complete response to the Office Action mailed June 2, 2004. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

Date: _____

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